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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,573	01/16/2004	Claude Singer	1662/52804	7978

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	SINGER ET AL.
Examiner Simon J. Oh	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenconi *et al.*

(WIPO Document No. WO 00/58268) in view of Bruna *et al.* (WIPO Document No. WO 00/07568)

The Tenconi *et al.* document discloses processes for the preparation of gabapentin from gabapentin hydrochloride (See Abstract). The process comprises the steps of preparing an aqueous solution of gabapentin hydrochloride; adjusting the pH of the solution, preferably to about its isoelectric point of pH 7.14, by the addition of a base; diafiltration through a selective membrane; concentrating and then evaporating the retentate; and precipitation of gabapentin by the addition of an alcohol. This process avoids the use of drastic process conditions, such as high temperatures, so as to avoid the undesired formation of gabapentin lactam (See Page 3, Line 7 to Page 4, Line 30; and Pages 4-7, Examples 1-3). The Tenconi *et al.* reference also discloses a prior art process, disclosed in WIPO Document No. WO 98/28255. The examiner notes the common inventorship and ownership of this reference and the instant application. The basic steps of the process are disclosed, which the examiner further notes are the same basic steps of

gabapentin preparation disclosed in the instant application (See Page 2, Line 15 to Page 3, Line 6).

The Tenconi *et al.* document does not disclose pharmaceutical compositions comprising gabapentin.

The Bruna *et al.* document discloses coated particles of γ -aminobutyric analog, having a lactam content of less than 0.5 % by weight of the analog (See Abstract). As the Bruna *et al.* document was originally published in French, an English language equivalent is provided, U.S. Patent No. 6,488,964 B2. For the sake of convenience, all citations from the Bruna *et al.* document will be made to sections in the U.S. patent reference. The coated-particle gabapentin compositions may comprise various excipients, such as methacrylate polymers and copolymers, cellulose polymers, sugars and sugar derivatives, polyols and polyol derivatives, artificial sweeteners, colloidal silica, precipitated silica, talc, sodium carboxymethylcellulose, and cross-linked polyvinylpyrrolidone (See Column 3, Line 56 to Column 5, Line 4). Stability tests at various conditions, including at 25°C and 60 % relative humidity, were conducted, in which various embodiments of the disclosed compositions demonstrated stability against lactam formation (See Examples 1-3).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. The prior art methods of gabapentin preparation, as disclosed in Tenconi *et al.* and in the WO 98/28255 reference, demonstrate processes that produce gabapentin in such a way as to minimize lactam formation. The Bruna *et al.* document demonstrates that composition formulation techniques can also contribute to the minimization of lactam formation. It is the

position of the examiner that by these formulation techniques, in addition to the prior art methods of gabapentin preparation, one of ordinary skill in the art would be motivated to take the disclosures of the prior art and combine them, as the references of the prior art both state the minimization of lactam formulation as a desirable feature. It is also the position of the examiner that one of ordinary skill in the art can take the gabapentin prepared by methods disclosed in the Tenconi *et al.* reference and incorporate them into the compositions of Bruna *et al.* with a reasonable expectation of success. It is further the position of the examiner that, through routine experimentation, one of ordinary skill in the art can create gabapentin compositions that fit the criteria set forth in the limitations of the instant claims with a reasonable expectation of success. The claim limitation drawn to the pH of the gabapentin is considered obvious in view of the disclosure in Tenconi *et al.* in which the pH of the gabapentin hydrochloride is adjusted to pH 7.14. Even if the applicant disagrees with this position, the examiner does not consider this limitation to impart a patentable distinctiveness in formulating a storage-stable composition over what has already been disclosed by Bruna *et al.* Additionally, the particular selection of Aerosil 200 as an excipient in the instantly claimed composition is not considered to be a critical feature over the general disclosure in Bruna *et al.* of the use of colloidal silica and precipitated silica. Thus, the instantly claimed invention is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sjo

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600